UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ISIS PHARMACEUTICALS, INC., a Delaware Corporation,

Plaintiff,

v.

SANTARIS PHARMA A/S CORP., a Delaware Corporation, and SANTARIS PHARMA A/S, a Danish Corporation,

Defendants.

AND RELATED COUNTERCLAIMS.

Case No. 3:11-cv-2214-GPC-KSC

ORDER GRANTING PLAINTIFF'S MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT

(ECF NO. 95)

INTRODUCTION

Before the Court is Plaintiff's Motion for Leave to File a First Amended Complaint, (ECF No. 95), which has been fully briefed, (ECF Nos. 104, 109), and which the Court finds suitable for disposition without oral argument, see CivLR 7.1.d.1. After considering the parties' submissions and the record in this matter, and for the reasons that follow, the Court hereby **GRANTS** Plaintiff's Motion for Leave to File a First Amended Complaint.

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BACKGROUND

Plaintiff filed suit on September 22, 2011, alleging infringement of two of its patents: U.S. Patent No. 6,326,199, "Gapped 2' Modified Oligonucleotides" ("'199 Patent") and U.S. Patent No. 6,066,500 "Antisense Modulation of Beta Catenin Expression" ("'500 Patent"). (ECF No. 1.) Both the '199 Patent and the '500 Patent cover methods and compounds related to the modification of genetic material.

Ribonucleic acid, or RNA, is a single-stranded molecule that carries genetic instructions. Messenger RNA, or mRNA, carries genetic instructions from a cell's nucleus to the cell's cytoplasm, where it provides instructions for the production of proteins. Nucleotides from the basic structural unit of nucleic acids like mRNA.

The '199 Patent covers the synthesis and use of short strands of nucleotides called oligonucleotides, antisense molecules, or – very broadly – macromolecules. The '199 Patent claims a method whereby antisense molecules are hybridized with complimentary strands of mRNA in a target cell to modify the target cell's behavior in some way.

To ensure successful hybridization, the antisense molecules covered by the '199 Patent possess features that make degradation of the molecule less likely and that make binding with the complimentary strand more likely.

If successfully hybridized, the antisense molecule modifies the target cell to, for example, decrease production of a certain protein. Indeed, the '500 Patent covers the synthesis and use of an antisense molecule that specifically reduces production of the protein Beta catenin – a protein whose overproduction has been tied to certain cancers.

Plaintiff alleges in its Complaint that Defendants have used the molecules claimed by the '199 Patent, and the method of contacting cells with those molecules also claimed in the '199 Patent, to "identify [gene] targets and/or to screen gapmer ... antisense molecules for activity inhibiting a target." Plaintiff alleges Defendants sell and offer for sale in the U.S. the patented methods of the '199 Patent. Plaintiff further alleges that Defendants have infringed the '500 Patent by offering for sale and selling

antisense compounds that inhibit Beta catenin production.

Plaintiff bases its infringement contentions on four agreements between Defendants and various U.S. pharmaceutical companies: a January 4, 2011 agreement with Pfizer, Inc.; a July 27, 2006 agreement with Enzon Pharmaceuticals, Inc.; an August 24, 2009 agreement with Shire PLC; and a December 19, 2007 agreement with GlaxoSmithKline. Plaintiff alleges each of the agreements infringe the '199 Patent (and that the Enzon agreement also infringes the '500 Patent) because the agreements require Defendants to supply the above pharmaceutical companies with antisense molecules that are covered by the '199 and '500 Patents for use in connection with therapeutic targets identified by the pharmaceutical companies.

On December 8, 2011, Defendants filed an answer and counterclaims against Plaintiff. (ECF No. 12.) On December 12, 2011, Plaintiff filed a reply to Defendants' counterclaims. (ECF NO. 14.)

Thereafter, before a case management conference was held (and thus before discovery commenced), Defendants filed a motion for summary judgment. (ECF No. 17.) Defendants asserted they are entitled to judgment as a matter of law pursuant to the safe harbor provision set forth in 35 U.S.C. § 271(e)(1).[1] Defendants claimed their use of the antisense technology falls within the safe harbor provision because the only purpose for Defendants' use of the technology is to develop antisense drugs that target conditions that have already been identified by Defendants' pharmaceutical partners

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[1] Section 271(e)(1) provides: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs[.]"

The safe harbor provision applies "where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, the use is 'reasonably related' to the 'development and submission for information . . . under federal law.'" Merck KGaA v. Integra Lifesciences I, Ltd, 545 U.S. 193, 207 (2005).

The safe harbor provision does not apply when a biological compound is used to perform "basic scientific research" or as a "research tool." Id. at 205-06.

in the U.S. That is, Defendants claimed their use of the antisense technology falls within the safe harbor provision because Defendants' pharmaceutical partners ultimately use Defendants' work in connection with seeking FDA approval of antisense drugs.

On September 19, 2012, prior to the case's transfer to this Court, Judge Moskowitz denied Defendants' Motion for Summary Judgment without prejudice. (ECF No. 53.) Judge Moskowitz found Defendants had offered insufficient evidence as to Defendants' specific uses of the infringing compounds, methods, and processes. Judge Moskowitz further found a dispute of material fact as to whether Defendants do not perform any antisense technology work until a therapeutic target has already been identified by a pharmaceutical partner. Judge Moskowitz concluded, stating, "To the extent [Defendants] [are] selling and/or licensing infringing 'platform' technology so that another company can 'discover and develop' drug candidates—rather than developing and/or licensing/selling specific drug candidates itself—[Defendants] could be using or selling patented technology to perform 'basic scientific research.'" And such use, of course, would not fall within the safe harbor.

In denying Defendants' Motion for Summary Judgment, Judge Moskowitz permitted the parties 120 days to conduct limited discovery related to the issues raised by Defendants' safe harbor defense. Judge Moskowitz further granted Defendants leave to re-file a motion for summary judgment on the safe harbor issue within 30 days following close of the limited discovery period. In a separate order, Judge Moskowitz stayed all discovery and disclosure obligations unrelated to the Defendants' safe harbor defense until January 16, 2012. (ECF No. 54.)

Judge Crawford held a CMC on July 20, 2012, and issued a case management conference order on July 26, 2012 ("First Scheduling Order"). (ECF Nos. 41, 42.) The First Scheduling Order set a deadline of August 20, 2012, to file "[a]ny motion to join other parties, to amend the pleadings, or to file additional pleadings." (ECF No. 42.)

On October 12, 2012, the case was transferred to this Court. (ECF No. 57.)

On January 31, 2013, Judge Crawford found good cause to vacate the First Scheduling Order. (ECF No. 94.) Judge Crawford gave Plaintiff until February 1, 2013 to file a motion for leave to file a first amended complaint, continued the stay limiting discovery to the safe harbor issue until April 5, 2013, and informed the parties that a new briefing scheduling on Defendants' safe harbor summary judgment motion would be set following this Court's ruling on Plaintiff's motion for leave to amend. Plaintiff thereafter filed the instant motion.

DISCUSSION

I. Legal Standard

Leave to amend a complaint after a responsive pleading has been filed "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Granting leave to amend rests in the sound discretion of the trial court. Int'l Ass'n of Machinists & Aerospace Workers v. Republic Airlines, 761 F.2d 1386, 1390 (9th Cir. 1985). This discretion must be guided by the strong federal policy favoring the disposition of cases on the merits and permitting amendments with "extreme liberality." DCD Programs Ltd. v. Leighton, 833 F.2d 183, 186 (9th Cir. 1987). "Amendments seeking to add claims are to be granted more freely than amendments adding parties." Union Pacific R.R. Co. v. Nevada Power Co., 950 F.2d 1429, 1432 (9th Cir. 1991).

Courts should consider five factors in determining whether a plaintiff ought to be granted leave to amend: undue delay, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, prejudice to the opposing party, and futility of amendment. Foman v. Davis, 371 U.S. 178, 182 (1962). "Absent prejudice, or a strong showing of any of the remaining Foman factors, there exists a presumption under Rule 15(a) in favor of granting leave to amend." Eminence Capital, LLC v. Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003) (emphasis added).

II. Analysis

Plaintiff seeks to amend its Complaint by: (1) adding an allegation of direct infringement under 35 U.S.C. § 271(b); (2) expand the factual allegation of direct

infringement to include new information on Defendants' previously undisclosed relationship with a third party; and (3) add a third cause of action for Defendants' infringement of U.S. Patent No. 6,440,739 ("'739 Patent").

Plaintiff argues it should be granted leave to amend because all of the Foman factors tip in its favor. Plaintiff asserts it has not unduly delayed in seeking leave to amend because Plaintiff was not aware of the facts underlying its proposed amendments until November 2012. Plaintiff further asserts it is seeking leave to amend in good faith and that its amendments are not futile. Plaintiff argues its amendments will not prejudice Defendants because of the relatively early stage of these proceedings: discovery has only proceeded on a limited basis, no full scheduling order has issued, and the parties have not yet begun complying with the many requirements found in the Patent Local Rules. Plaintiff lastly argues that Judge Crawford's January 31, 2013 order vacating the First Scheduling Order provides further support for Plaintiff's request for leave to amend.

Defendants argue in response that Plaintiff has unduly delayed in seeking leave to amend because Plaintiff had knowledge of the facts underlying its proposed amendments at the time Plaintiff filed its initial complaint and because Plaintiff was not diligent with respect to adding its proposed claim for infringement of the '739 Patent. Defendants argue Plaintiff's amendments would prejudice Defendants by (1) potentially delaying the end of this litigation, as Defendants' safe harbor summary judgment motion will be dispositive of the entire case; and (2) expanding discovery into the activities of several third parties. Defendants argue that, at a minimum, Plaintiff should be denied leave to amend without prejudice and allowed to re-file the motion after this Court's ruling on Defendants' renewed summary judgment motion.

The Court first notes that Defendants do not argue Plaintiff's proposed amendments are futile or sought in bad faith; thus, the Court does not consider those factors. As to delay, the Court finds Plaintiff did not unduly delay in seeking leave to file a first amended complaint. Given the complexity of this case and the number of

documents produced in the limited discovery that has occurred thus far, the Court finds any delay by Plaintiff was reasonable. The Court further finds Defendants have not demonstrated they would be significantly prejudiced by Plaintiff's proposed amendments given the relatively early stage of these proceedings. The Court therefore concludes that Defendants have not made a showing sufficient to overcome the "presumption under Rule 15(a) in favor of granting leave to amend." See Eminence Capital, 316 F.3d at 1052.

CONCLUSION

After a careful review of the parties' submissions and the records in this matter, and for the foregoing reasons, **IT IS HEREBY ORDERED** that:

1. Plaintiff's Motion for Leave to File a First Amended Complaint, (ECF No. 95), is **GRANTED**;
2. The hearing on Plaintiff's Motion for Leave to File a First Amended Complaint, currently set for April 26, 2013, is **VACATED**;
3. Plaintiff shall file its First Amended Complaint on or before **April 26, 2013**;
4. The limited discovery period having concluded on April 5, 2013, all discovery and disclosure obligations are **STAYED** pending this Court's decision on Defendant's renewed motion for summary judgment on the safe harbor issue;
5. Notwithstanding Judge Crawford's instructions to contact her chambers to set a status conference, (see ECF No. 94 at ¶ 5), Defendants' counsel is instead directed to contact this Court's chambers on or before **April 26, 2013**, to obtain a hearing date for Defendants' renewed motion for summary judgment on the safe harbor issue.

DATED: April 23, 2013

HON. GONZALO P. CURIEL
United States District Judge